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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,866	07/07/2003	Jane Hirsh	CP 100	8191

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EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
ART UNIT	**PAPER NUMBER**
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/614,866	HIRSH ET AL.	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,15-29 and 33-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,15-29 and 33-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of amendment and response dated 12-8-06 is acknowledged.

Claims 1-13, 15-29 and 33-38 are pending in the instant application. Claims 14 and 30-32 have been canceled.

Applicants have made substantial amendments to the pending claims. In view of the previously made election requirement and the present amendments, it is to be noted that claims 2 (independent claim), 4-7, 9-13, 15-26 and 33-36 read on the elected species i.e., a lipophilic derivative of a drug. Accordingly, claims 2, 4-7, 9-13, 15-26 and 33-36 have been considered for examination and claims 1, 3, 8, 27-29 and 37-38 have been withdrawn as being non-elected.

Response to Arguments

Applicant's arguments with respect to claims 1-13, 15-29 and 33-38 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim2, 4-7, 9-13, 16-26 and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,310,072 to Smith et al (Smith) in view of US 6,696,088 (Oshlack et al).

Smith teaches pharmaceutical compositions comprising a combination of mu and kappa opioid agonists such as morphine and oxycodone respectively. In particular,

Smith teaches salts of the opioid agonists such as pectinate and terephthalate, both of which have been described in the instant application as lipophilic derivatives (col. 5, L 5-10, L 41-43). Smith suggests oral and subcutaneous methods of administering the composition, wherein the controlled release dosage forms are coated with hydrophobic polymers such as higher fatty alcohols (col. 8, L 49-63). While the reference suggests controlled release as well as immediate release of the drugs, Smith does not teach a formulation of oxycodone that is dispersed in the insoluble formulation for preventing the immediate release of the drug upon loosing its integrity.

Oshlack teaches a tamper resistant and also abuse resistant oral opioid formulation, in which the active agent is not delivered immediately (col. 5, col. 6, L 42-60 & lines bridging col. 8-9). Oshlack teaches the same active agents that are claimed and in particular oxycodone (entire col. 14 & col. 16, L 1-19) and suggests salts of the opioid compounds such as sulfates, methanesulfonate, benzenesulfonates, phosphates etc (col. 11, L 45-61), which are dispersed in a non-releasable matrix or as coated particles made of hydrophobic and water-insoluble material. The latter hydrophobic material is selected from the group consisting of ethyl cellulose, cellulose acetate phthalate, acrylic polymers, fatty acids, fatty alcohols, waxes etc (col. 27, L 25-col. 29, L 37). Preferably, Oshlack teaches hydrophobic materials such as waxes, fatty acids etc (col. 28, L18-54). Oshlack further teaches coating of the non-releasable dosage forms with materials such a shellac, zein etc (col. 23, L 2-12), which admittedly reads on the enzyme degradable coating of the instant claims. Oshlack also teaches microparticles, coated microparticles and enteric coating materials such

Thus, Oshlack is also in the same field of endeavor as that of the instant i.e., preparing abuse resistant formulations of opioid analgesics and delaying the immediate release of the drug that results in abuse of the substance.

While instant claims recite lipophilic derivatives of the drug, Oshlack teaches salts of the opioid drugs such as organic amine salts (picoline, ethanolamine, triethanolamine, dibenzyldiethyldiamine etc., (col. 11, L 45-52), which read on the instant lipophilic derivatives.

Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use the controlled release formulation i.e., the insoluble material selected from fats, fatty alcohols, waxes and insoluble cellulose polymers of Oshlack for preparing a controlled release dosage formulation of terephthalate or pectinate salt of oxycodone because Oshlack teaches that opioid analgesics have a potential for the development of tolerance and physical dependence with repeated opioid use resulting in addiction (abuse) and that the abuse can be controlled by sequestering the bioavailability of the drug upon administration i.e., by preventing the immediate availability of the drug.

2. Claims 15 is are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,310,072 to Smith et al (Smith) in view of US 6,696,088 (Oshlack et al) as applied to claims s 2, 4-7, 9-10, 16-26 and 33-36 above, and further in view of US 6,048,736 to Kosak or US 5,756,483 to Merkus ('483, previously cited in the non-final rejection).

Smith and Oshlack, discussed above, do not teach the claimed complexes in particular the cyclodextrin complexes.

Kosak teaches cyclodextrin polymers for carrying drugs and other active agents and for controlled release of active agents. Kosak teaches that when the polymers are conjugated to the cyclodextrin molecules, the drugs can be designed solely for efficacy without regard for solubility and their targeted release. Kosak teaches employing a number of active agents with cyclodextrin including narcotics (col.3).

'483 teach compositions comprising morphine, apomorphine, ergotamine etc., compounds and their administration in combination with cyclodextrin or a polysaccharide (abstract, examples and col. 4, lines 50-67). '483 teach that cyclodextrin and other saccharides increase the stability of the drug and thus increase their bioavailability. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to prepare morphine and oxycodone compositions comprising cyclodextrin because both Kosak and '483 suggests that drug complexes with cyclodextrin improves the solubility and their targeted release. A skilled artisan would have expected to release the drug combination of Smith in a delayed (Oshlack) and yet targeted fashion (Kosak) so as to further improve drug abuse of the opioid drugs.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.00 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AU 1615
March 20, 2007

LAKSHMI S. CHANNAVAJJALA
PRIMARY EXAMINER